

REMARKS

Applicants' attorney spoke with the Examiner via telephone conference on June 2, 2004, and thanks the Examiner for her time and courtesy during that interview. The contents of a draft of this amendment were discussed. The Examiner indicated that the previously-cited art did not read on the claims of this Amendment, which reflects changes made during the interview.

Double Patenting

An executed terminal disclaimer is attached with respect to co-pending and commonly-owned U.S. Patent Application Serial No. 09/886,074. As a result, Applicants request withdrawal of the provisional double patenting rejection as to claims 37-43, 55-58 and 77-84.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 37-44

Claim 37 has been amended to more positively recite the anastomosis device, claiming "[a]n anastomosis system for connecting a graft vessel to a target vessel, the applicator comprising: a one-piece anastomosis device; a first tube configured to receive said anastomosis device; a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another to deploy said anastomosis device,

wherein said deployed anastomosis device has two spaced-apart flanges; and a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out of the side of the tube.”

In contrast, U.S. Pat. No. 6,024,748 to Manzo (“Manzo”) neither discloses nor suggests every element of amended claim 37. Instead, Manzo discloses a plurality of individual clips rather than a “one-piece anastomosis device.” (*e.g.*, Figures 8-9; column 3, line 3; column 6, lines 12-15; column 9, lines 43-48; column 11, lines 13-16).

In addition, U.S. Pat. No. 5,833,698 to Hinchliffe et. al. (“Hinchliffe”) neither discloses nor suggests every element of amended claim 37. Hinchliffe discloses an anastomosis device that has a ring-shaped body and a number of barbs extending from it. (*e.g.*, Figure 25; column 11, lines 12-14). However, Hinchliffe neither discloses nor suggests a deployed anastomosis device having two spaced-apart flanges.

Thus, neither cited reference discloses nor suggests each and every element claimed in amended claim 37, and Applicants believe claim 37 is in condition for allowance. Claims 38-44 depend directly or indirectly from claim 37, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 45-49

Amended claim 45 claims “[a]n anastomosis applicator for deploying an anastomosis device to connect a graft vessel to a target vessel, the applicator comprising: a first tube configured to receive a one-piece anastomosis device, wherein said device comprises a distal end and a proximal end and a longitudinal axis; a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another, configured for deployment of the anastomosis device, and configured to remain outside the graft vessel; and wherein the applicator has a pre-deployment configuration where at least one tube

extends beyond the distal end of the device.”

In contrast, U.S. Pat. No. 5,976,178 to Goldsteen (“Goldsteen”) neither discloses nor suggests every element of amended claim 45. Instead, Goldsteen discloses a plurality of tubes configured for motion through the graft vessel. (*e.g.*, Figures 18, 23, 24; column 14, lines 1-6).

The same discussion of Manzo applies here as applied in the discussion of claims 37-43 above.

Thus, neither cited reference discloses nor suggests each and every element claimed in amended claim 45, and Applicants believe claim 45 is in condition for allowance. Claims 46-49 depend directly or indirectly from claim 45, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 55-58

Claim 55 claims “[a]n anastomosis tool for use in connecting an end of a graft vessel to the side of a target vessel, the tool comprising a vessel penetrating member configured to penetrate the target vessel and configured for withdrawal outside the lumen of the graft vessel, wherein the tool is configured to penetrate the target vessel and deliver a one-piece anastomosis device to connect the graft vessel to the target vessel.”

In contrast, Goldsteen neither discloses nor suggests each and every element of amended claim 55. Instead, Goldsteen discloses a collapsible tip 412 configured for withdrawal through the lumen of the graft vessel. (*e.g.*, Figures 14, 15, 18, 23, 24; column 12, lines 27-28; column 14, lines 4-5). Indeed, the collapsible tip 412 is collapsible in order to allow it to be removed through the graft conduit after the anastomosis is complete; because “all or substantially all of the necessary apparatus is inserted into the patient via the patient’s

existing body organ tubing” using a catheter 210, the tip is necessarily removed from the graft conduit. (*e.g.*, column 2, lines 41-43; column 12, line 66 through column 13, line 1).

Thus, Goldsteen neither discloses nor suggests each and every element claimed in amended claim 55, and Applicants believe claim 55 is in condition for allowance. Claims 56-58 depend directly or indirectly from claim 55, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 77-81

Amended claim 77 claims “[a] method of performing anastomosis between a graft vessel and a target vessel, the method comprising: providing a one-piece anastomosis device; receiving said anastomosis device on an anastomosis device applicator having a vessel penetrating member; connecting a graft vessel to said anastomosis device on the anastomosis device applicator; creating an opening in the target vessel with the vessel penetrating member of the anastomosis device applicator; advancing said anastomosis device into the penetration in the target vessel; and deploying said anastomosis device with the anastomosis device applicator to connect the graft vessel to the target vessel.”

In contrast, Gifford neither expressly nor inherently discloses creating an opening in the target vessel with the vessel penetrating member of the anastomosis device applicator. Instead, Gifford discloses an applicator in which an anvil is inserted into the lumen of the target vessel through a pre-existing slit, such as formed “with a scalpel or other sharp instrument” separate from the applicator. (*e.g.*, Figures 4, 5A; column 18, lines 60-64). Thus, Gifford neither expressly nor inherently describes creating an opening in the target vessel with the vessel penetrating member of the anastomosis device applicator.

Thus, Gifford neither expressly nor inherently describes each and every element claimed in amended claim 77, and Applicants believe claim 77 is in condition for allowance.

Claims 78-81 depend directly or indirectly from claim 77, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claim 79

Claim 79 depends from independent claim 77, which is believed to be allowable.

Thus, claim 79 is believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 82-84

Among other elements, claim 82 claims "connecting a graft vessel to ~~the~~ said anastomosis device on the anastomosis device applicator with an end of the graft vessel passing out a side hole of at least one of the first and second tubes." In contrast, Gifford neither teaches nor suggests an end of the graft vessel passing out a side hole of at least one of the first and second tubes. Instead, Gifford teaches the graft vessel passing along a longitudinal passage in the applicator. (e.g., column 19, lines 28-31; column 20, lines 27-31;

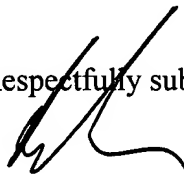
column 54, line 65 through column 55, line 15; Figures 5F, 7C, 45A-D). Nowhere does Gifford disclose or suggest a side hole in any tube.

Thus, Gifford neither teaches nor suggests each and every element claimed in amended claim 82, and Applicants believe claim 82 is in condition for allowance. Claims 83-84 depend directly or indirectly from claim 45, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar
Attorney for Applicants
Reg. No. 45,076
Tel. No. (650) 331-7162
Chief Patent Counsel
Cardica, Inc.